

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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JANE DOE, *individually and as*
Parent/Guardian of BABY DOE,

Plaintiffs,

-against-

MERCK & CO. INC.; HEALTH AND
HUMAN SERVICES; THOMAS PRICE,
M.D., *in his official capacity as Secretary*
of Health and Human Services; SCOTT
GOTTLIEB, M.D., *in his official*
capacity as Commissioner of the Food
and Drug Administration, a division of
Health and Human Services; and the
UNITED STATES OF AMERICA,

Defendants.
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MEMORANDUM AND ORDER

Case No. 16-CV-04005 (FB) (RLM)

Appearances:

For Doe:

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For Merck:

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For the Federal Defendants:

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By: LAYALIZA K. SOLOVEICHIK

BLOCK, Senior District Judge:

Minor plaintiff Baby Doe and his mother, Jane Doe (collectively, "Doe"), has filed suit against (1) Merck & Co. Inc. ("Merck"); and (2) Health and Human Services, Thomas Price (in his official capacity as Secretary of Health and Human Services), Scott Gottlieb (in his official capacity as Commissioner of the Food and

Drug Administration), and the United States of America (collectively, “Federal Defendants”). Pending before the Court are Merck’s and the Federal Defendants’ respective motions to dismiss Doe’s Third Amended Complaint (“TAC”). The Court grants both motions and dismisses the TAC with prejudice.

BACKGROUND

Doe alleges that Merck produced a measles, mumps, and rubella (“MMR”) vaccine that was administered to him in 1999 and caused him to develop autism.¹ TAC ¶¶ 112, 117. New York Public Health Law requires students attending post-secondary educational institutions to be vaccinated for MMR, which includes receiving MMR booster shots. *See* N.Y. Pub. Health Law §§ 2164, 2165.² Doe worries that another dose of the vaccine could “seriously injure[] [him], substantially aggravate[] his existing condition,” or even kill him. Doe Opp. Br. at 8.

The TAC, to put it mildly, is enigmatic. Notwithstanding the requirements of Federal Rule of Civil Procedure 8(a), the basis for its claims and the claims’ respective causes of action are far from clear. Doe attempts to alleviate the confusion in his opposition brief. Although this arguably represents an impermissible

¹ The Court uses the term “autism” as a shorthand for “autism spectrum disorder,” which is a neurological disorder “affecting a person’s ability to communicate, form relationships, and/or respond appropriately to the environment.” Autism General Order #1, Dkt. No. 67 Ex. A n.2 (“Autism General Order #1”).

² The parties dispute whether the Public Health Law also requires immunization for residents at group home living facilities. Because the Court’s decision does not depend on the resolution of that question, it does not address it.

amendment to the complaint, *see O'Brien v. Nat'l Prop. Analytics Partners*, 719 F. Supp. 222, 229 (S.D.N.Y. 1989),³ the Court uses Doe's brief as an aid in understanding the TAC.

The TAC contains three counts. In Count One, Doe alleges violations of the National Childhood Vaccine Act of 1986 ("Vaccine Act") by both Merck and the Federal Defendants, for which he seeks damages. He also seeks damages in Count Two, where he alleges that Merck committed fraud and conspired with the government to commit fraud, all in an effort to maintain the license for its MMR vaccine. Finally, in Count Three, Doe seeks declaratory and injunctive relief, asking the Court to revoke Merck's MMR license and enjoin New York from requiring the MMR vaccine booster shot as part of its Public Health Law.

To better understand these counts and why they are meritless, the Court supplies a brief summary of the relevant legal framework and prior related litigation.

A. The Vaccine Act and the Vaccine Court

"To stabilize the vaccine market and facilitate compensation [for injuries caused by vaccines], Congress enacted the [Vaccine Act] in 1986." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011). The Act established a no-fault liability scheme (colloquially called the "Vaccine Court") operated by the United States

³ Not only are parties prohibited from using briefs as vehicles to amend complaints, but the Court also specifically disallowed any further amendments on December 20, 2016.

Court of Federal Claims. Petitioners who claim to have suffered a vaccine-related injury are required to file a claim in the Vaccine Court and name the Secretary of Health and Human Services as a defendant. A “Special Master” adjudicates the claim in a simplified proceeding with limited discovery and tight deadlines. So long as the alleged injury is listed in the “Vaccine Injury Table,” the petitioner does not have to prove causation (injuries not included in the table may be asserted but still require a showing of causation). Dissatisfied petitioners may appeal the Special Master’s decision to the Court of Federal Claims. Once a final judgment is issued, petitioners may either accept it or reject it and seek relief in a traditional tort suit. *See generally id.* at 228–30.

B. Omnibus Autism Proceeding

In the early 2000s, thousands of petitions were filed in the Vaccine Court on behalf of children who had developed autism. Some of the petitioners had received MMR vaccines, some had received vaccines containing the mercury-based preservative thimerosal (so-called “thimerosal containing vaccines” or “TCVs”), and some received combinations of the two. The Vaccine Injury Table did not include autism as a recognized injury for any of these vaccines.

To process the large number of petitions, the Office of Special Masters established an opt-in Omnibus Autism Proceeding (“OAP”), which was designed to determine causation through “test cases,” with the results then applicable to the

remaining petitions. These test cases were grouped by the vaccines that the petitioners received: those that received MMR vaccines only, those that received TCVs only, and those that received both MMR vaccines and TCVs. Petitioners who opted into the OAP were bound by the results of the test cases. If, for example, the MMR-only test cases demonstrated that MMR vaccines caused autism, petitioners who alleged that they developed autism after receiving an MMR vaccine (but not a TCV) would not need to prove causation. Likewise, if the MMR-only test cases showed no causation, that result would be applicable to any MMR-only petitioner who had opted into the OAP. *See* Autism General Order #1 at 3–4.

Doe’s case was selected as one of the TCVs-only test cases. TAC ¶ 116. In a decision that spanned over 200 pages, Special Master Vowell concluded that there was no scientific evidence of any causal link between TCVs and autism. *See CD v. Sec’y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250, at *1 & n.6, *201 (Fed. Cl. Mar. 12, 2010).⁴ Doe did not appeal this result. He also did not file any separate petition in the Vaccine Court alleging that his autism was caused by the MMR vaccine (as opposed to by a TCV).

⁴ Doe has waived the redaction of his name by citing to the Westlaw version of the Special Master’s decision, which contains his full name. Fed. R. Civ. P. 5.2(h); *see* TAC ¶ 116. The Court adopts Doe’s convention of using his initials in the caption when citing to that decision.

DISCUSSION

On a motion to dismiss, the Court accepts all factual allegations as true to determine whether they “state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

A. Claims Against Merck

1. *Count One*

Doe explains that he brings Count One under 42 U.S.C. § 300aa-11(a)(2), *see* Doe Opp. Br. at 20, which establishes the procedure that allows plaintiffs to file suit against vaccine manufacturers after administratively exhausting the claim in the Vaccine Court. It would thus seem that Doe is alleging that Merck’s MMR vaccine caused his autism, and that he is suing for that injury. As previously noted, however, Doe only alleged in the Vaccine Court that his injury was caused by a TCV, not an MMR vaccine. Because he has failed to exhaust his administrative remedies, the Court would lack jurisdiction over a claim against Merck for MMR-caused autism.⁵

In his opposition brief, Doe advances an altogether different explanation of

⁵ Doe argues that his TCV petition should be construed as extending to an MMR petition as well. In support, he cites the Special Master’s decision that noted that “the evidence adduced in the omnibus proceeding” could be used in “other cases.” *CD*, 2010 WL 892250 at *2. Not only does it not follow that shared evidence constitutes interchangeable petitions, but the sharing of evidence was actually only available “in additional cases presenting *the same theory of causation*.” *Id.* (emphasis added).

his claim. He alleges that Merck “tamper[ed]” with a separate OAP test case petition “by furnishing [the government] with an eleventh hour witness,” all in an effort “to discredit” that petitioner’s “laboratory evidence” and “attack[]” her “theory of causation in her MMR case that relied upon preliminary research.” Whatever this cryptic allegation may mean, it cannot form the basis of a § 300aa-11(a)(2) claim. No amount of “furnishing” or “discredit[ing]” perpetrated by Merck in the OAP could have resulted in a “vaccine-related injury or death” to Doe, not least of all because he received the vaccine in 1999 and the OAP did not begin until the 2000s.

2. *Count Two*

Doe alleges that Merck committed fraud in procuring and maintaining its license to manufacture and distribute its vaccines. He also alleges that Merck and the government have engaged in a civil conspiracy to commit fraud in furtherance of the same. In support of these allegations, Doe describes several events that all occurred in the 2000s and provides hazy insinuations of backroom deals and corporate-government plots aimed at concealing vital health information from the unwitting public. *See* TAC ¶¶ 171–200. In his opposition brief, Doe adds still more color to this claim. He summarizes the “legal issue for the District Court” as follows:

[W]hat does [a current Merck executive who was formerly employed by the Center for Disease Control and Prevention] know about the causal link between MMR and Autism, allegedly identified in the original Atlanta Autism Studies, and how children with mitochondrial disorders that are vaccinated can become autistic[?]

Doe Opp. Br. at 23.

Even taken as true, none of Doe's allegations can form the basis of a valid fraud claim against Merck. Nor is it relevant that the government once employed an individual who now works for Merck, even if said individual knew then or knows now about a causal link between MMR vaccines and autism. Putting aside the particularity requirements for fraud of Federal Rule of Civil Procedure 9(b), every alleged statement or omission made by a Merck employee occurred *after* Doe received the vaccine in 1999. Thus, Doe cannot prove reliance, which is fatal to his fraud claim. *See Schlaifer Nance & Co. v. Estate of Warhol*, 119 F.3d 91, 98 (2d Cir. 1997). Furthermore, because Doe cannot prove fraud, he cannot prove conspiracy to defraud. *Crigger v. Fahnestock & Co, Inc.*, 443 F.3d 230, 237 ("Under New York law, civil conspiracy to commit fraud, standing alone, is not actionable if the underlying independent tort has not been adequately pleaded." (quoting *Vasile v. Dean Witter Reynolds Inc.*, 20 F. Supp. 2d 465, 482 (E.D.N.Y. 1998) (alterations omitted))); *see also Marcus v. AT&T Corp.*, 138 F.3d 46, 57 n.2 (2d Cir. 1998) (observing that federal common law fraud and New York state common law fraud have "practically identical" standards); TAC ¶ 169 (citing cases interpreting New York law).

3. Count Three

In Count Three, Doe requests that the Court revoke Merck's license for

distributing its MMR vaccine and enjoin New York from requiring the vaccine.

The Court declines to exercise primary jurisdiction to grant such relief. The proper body to consider revocation of a vaccine manufacturer's license is the Food and Drug Administration. *See Ellis v. Tribute Television Co.*, 443 F.3d 71, 81 (2006) (describing primary jurisdiction). Not only are vaccine safety and licensing issues peculiarly within the FDA's expertise and discretion, *see id.* at 82–83, but the FDA has specifically established procedures for citizens to petition the agency to take administrative action that it has authority over, *see* 21 C.F.R. §§ 10.25, 10.30. An administrative petition is the proper mechanism for requesting the relief Doe seeks, not a claim for injunctive relief in this Court.

As for New York's vaccination requirements, that request is properly directed at the State of New York, which is not a party to this lawsuit. Doe inexplicably urges the Court to treat Merck as a state actor "acting under color of state law, as an agent of the United States government in the distribution/sale of the MMR vaccine to children required to attend school in New York State." Doe Opp. Br. at 25. Doe provides no analysis as to how or why Merck's role in providing and distributing vaccines would make it a state actor, nor why its role as an "agent of the United States government" would obviate the need for New York to be represented in this

lawsuit.⁶

B. Claims Against the Federal Defendants

1. Count One

Doe explains that he brings Count One against the Federal Defendants under the so-called “citizen’s action” of the Vaccine Act, 42 U.S.C. § 300aa-31. This section allows citizens to sue the Secretary of Health and Human Services “where there is alleged a failure of the Secretary to perform any act or duty [under the Act].”

Because § 300aa-31 only waives sovereign immunity as to the Secretary of Health and Human Services, the Court dismisses Count One as to all of the other Federal Defendants. As to the Secretary, Doe fails to allege any particular duty in which the Secretary was derelict. To the extent that duty is the general duty to ensure the safety of childhood vaccines, *see, e.g.*, 42 U.S.C. § 300aa-27, that claim is now precluded. As previously noted, Doe’s OAP petition, which named the Secretary as defendant, only alleged that a TCV induced his autism. Doe could have but did not allege that an MMR vaccine induced his autism. Claim preclusion now bars that

⁶ Doe misquotes *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), for the proposition that courts are required to “assess the constitutionality of each vaccination mandate individually,” Doe Br. at 25, and that such mandates may only be allowed in “highly circumscribed situations,” such as emergencies, epidemics, and the like, *id.* at 26. In *Jacobson*, the Court held that a Massachusetts mandate requiring smallpox vaccinations did not violate the Constitution. Doe’s quotations are taken entirely out of context. *See Jacobson*, 197 U.S. at 38 (establishing what amounts to a rational basis test for vaccination mandates).

claim in this Court. *See Curtis v. Citibank, N.A.*, 226 F.3d 133, 139 (2d Cir. 2000).

2. Count Two

The TAC labels Count Two as “*Merck’s* Fraud & Conspiracy to Commit Fraud” (emphasis added). Thus, by its own terms, Count Two is not brought as to the Federal Defendants. Furthermore, as explained *supra*, although the alleged conspiracy was with government officials, a conspiracy to commit fraud is not actionable without the underlying fraud.

3. Count Three

The Court declines to exercise jurisdiction to grant this relief. *See supra*.

CONCLUSION

In Doe’s OAP petition, Special Master Vowell lamented that

[u]nfortunately, the [Does] (and uncounted other parents of children with ASD) have relied upon practitioners and researchers who peddled hope, not opinions grounded in science and medicine. My heart goes out to parents like the [Does] who struggle daily, emotionally and financially, to care for their children, but I must decide cases based on the law and not sentiment.

2010 WL 892250, at *201. The Court must do likewise and dismisses the TAC with prejudice.

SO ORDERED.

/S/ Frederic Block
FREDERIC BLOCK
Senior United States District Judge

Brooklyn, New York
March 21, 2019